

**On protective immunization against meningococcus C (with conjugate vaccine)**

Meningococci (*Neisseria meningitidis*) are bacteria. 13 different serogroups have been identified to date. Serogroups A, B, C, and W are responsible for epidemics worldwide. Around 300 to 400 people in Germany, the majority of them small children, school children, and adolescents, come down with a severe meningococcal infection each year. Ca. 70% of these illnesses are caused by serogroup B, and 20 to 30% were caused by serotype C prior to the introduction of the standard vaccination for children and adolescents (now it is ca. 16%). A vaccine against illnesses caused by serotype B has been available since the end of 2013. However, the vaccine being discussed here targets serogroup C meningococci exclusively.

Meningococci are spread from person to person with respiratory air (droplet infection). They can trigger various invasive (affecting the entire body) severe illnesses, the most common being purulent meningitis (inflammation of the cerebral membrane) and life-threatening sepsis (blood poisoning). The onset of meningitis is sudden, with high fever, vomiting, severe headaches, and stiffness of the neck. Seizures and paralysis can also occur. The symptoms are usually less characteristic in very young children. The course of septic diseases is similar to that of meningitis, although the former are usually characterized by a dramatic disease progression. Skin hemorrhages are indications of a severe invasive disease progression. In cases that become septic, death can occur within just a few hours. A decisive factor in the event of a suspected invasive meningococcal disease is prompt referral to an intensive care unit, perhaps also the initiation of an antibiotic treatment before the hospital admission. But even a treatment started in a timely fashion cannot always prevent death or severe permanent damage (central nervous system damage, amputations as a consequence of severe tissue damage). Nearly 10% of patients with meningococcal infections still die, and the proportion is especially high for serotype C illnesses. Protective immunization is therefore the decisive preventive measure.

**Vaccine**

The vaccine contains fractions of the bacterial cell wall (oligosaccharides, polysaccharides) of the pathogen. It only provides protection against infections by serogroup C meningococci and can be administered from an age of 2 months. At-risk infants in the 1<sup>st</sup> year of life receive 1 or 2 vaccinations, depending on the vaccine used and the age. Children older than 1, adolescents, and adults are vaccinated once. A booster vaccination is recommended in the 2<sup>nd</sup> year of life if the basic immunization was started in the 1<sup>st</sup> year of life.

The vaccine is administered by intramuscular injection. Your doctor can tell you about the beginning and duration of the protection given by the vaccination. Based on the available data, there are no recommendations for a booster vaccination (see above for the exception).

The meningococcal C vaccination can be administered simultaneously with a second (another) vaccination, but at different sites (e.g., right and left thigh, right and left upper arm); tolerance and efficacy are not negatively influenced in the event of a simultaneous vaccination. Your doctor will tell you about exceptions to this rule.

**Who should get vaccinated?**

According to the vaccination calendar, meningococcal C immunization with a single vaccine dose is recommended for all children in the 2<sup>nd</sup> year of life. According to the Standing Committee on Immunization (STIKO), any vaccinations not administered at the recommended time should be made up by the time that the individual in question turns 18.

In principle all children older than 2 months, adolescents, and adults can be vaccinated if this immunization is desired or recommended by a doctor. The STIKO furthermore recommends immunization especially for persons at high risk for infections or complications. Persons with immune deficiencies or without a spleen or with a non-functional spleen, for example, are especially at-risk. A quadrivalent vaccine that also provides protection against other meningococcal groups (A, C, W, and Y), and possibly a vaccine for meningococcus B as well, should be administered to these persons. At-risk laboratory personnel should also be vaccinated against these meningococcal groups. Along with chemoprophylaxis (with antibiotics), unvaccinated close contacts should get a vaccination as soon as possible. If meningococcal C infections occur frequently in regions or in community facilities in Germany, health authorities may issue a call for immunization in order to prevent the disease from spreading. School children and students staying for prolonged periods in countries in which immunization against type C is recommended in general or specifically for this age group should be vaccinated. This likewise applies to travel in countries for which the health authorities have recommended vaccination for a limited period because of local outbreaks. Vaccination with a quadrivalent vaccine (A, C, W, Y) is recommended or prescribed for persons traveling to areas with meningococcal epidemics and coming into close contact with the local population. For example, this applies to pilgrimages (Hajj, Umrah) to Saudi Arabia or trips to the African meningitis belt.

**Who should not be vaccinated?**

Persons suffering from an acute disease with a fever requiring treatment should not be vaccinated. Persons with hypersensitivity to components of the vaccine should likewise not be vaccinated. Although there are no indications of negative impacts of the vaccination during pregnancy, the benefits and risks of a meningococcal C vaccination must be assessed thoroughly in pregnant women. The vaccinator will advise you regarding any further questions.

**Behavior after the vaccination**

Although the vaccine recipient needs no special care, unaccustomed physical strain during the 3 days after the vaccination should be avoided. The doctor should be informed accordingly before vaccinating persons who tend to experience cardiovascular reactions or with a known history of immediate (Type 1) hypersensitivity.

**Possible local and general post-vaccinal reactions**

In addition to the sought-after immunity and thus protection from the disease, after the vaccination redness, sensitivity to pressure, and painful swelling can occur very frequently ( $\geq 10\%$  of the vaccine recipients) at the vaccination site. This is an expression of the body's normal reaction to the vaccine and usually occurs within 2 to 3 days, rarely persisting longer than that. In rare cases these local reactions are more intense and thus limit mobility. Also within 1 to 3 days (and rarely persisting longer than that), 1 to  $\geq 10\%$  of the vaccine recipients may also experience general symptoms such as a temperature increase as high as 38°C (rarely as high as 39.5°C), drowsiness, restless sleep, or gastrointestinal complaints (nausea, vomiting, diarrhea), and irritability (children). Headaches as well

as muscle and joint pain or discomfort can also occur. As a rule the aforementioned reactions are temporary and quickly subside without any further consequences.

**Are post-vaccinal complications possible?**

Post-vaccinal complications are very rare consequences of immunization that exceed the normal extent of a post-vaccinal reaction. They have significant adverse impacts the health of the vaccine recipient. Very rarely, immunization with meningococcal C conjugate vaccine can induce allergic reactions of the skin (e.g., rash, itching, and hives) or of the respiratory passages, which can lead to shock in isolated cases. In isolated cases, febrile convulsion has been observed in conjunction with a temperature increase in infants or small children, which as a rule subsides with no further consequences. Brief, shock-like episodes with unresponsiveness and loss of muscle tone, which quickly subsided with no further consequences, have also been reported in isolated cases.

**Advice on possible side effects by the vaccinator**

As a supplement to this information leaflet, your doctor will propose an information discussion. The vaccinator is also at your disposal for advice should you experience any symptoms more severe than the rapidly subsiding local and general reactions mentioned above.

You can contact the vaccinator at:

**Disclaimer**

The translation of the original of the information leaflet (version: 04/2016) was made with the kind permission of German Green Cross (*Deutsches Grünes Kreuz e.V.*) by order of the Robert Koch Institute. The German text is authoritative. No liability shall be accepted for possible translation errors, nor for the up-to-datedness of the present translation in the event of subsequent revisions of the German language original.

**Name** \_\_\_\_\_

Name

**Immunization against meningococcus C (with conjugate vaccine)***Schutzimpfung gegen Meningokokken C – mit Konjugatimpfstoff*

Enclosed is an information leaflet on the administration of the vaccination against meningococcus C. It contains the essential details on the diseases that can be prevented by the vaccination, the vaccine, the vaccination, behavior after the vaccination, and on post-vaccinal reactions and possible post-vaccinal complications.

*Anliegend erhalten Sie ein Merkblatt über die Durchführung der Schutzimpfung gegen Meningokokken C. Darin sind die wesentlichen Angaben über die durch die Impfung vermeidbaren Krankheiten, den Impfstoff, die Impfung, das Verhalten nach der Impfung sowie über Impfreaktionen und mögliche Impfkomplicationen enthalten.*

Before the vaccination is administered, the following additional details are requested:

*Vor der Durchführung der Impfung wird zusätzlich um folgende Angaben gebeten:*

1. Is the vaccine recipient presently healthy?

*Ist der Impfling gegenwärtig gesund?*

Yes (*Ja*)

No (*Nein*)

2. Does the vaccine recipient have any known allergies?

*Ist bei dem Impfling eine Allergie bekannt?*

Yes (*Ja*)

No (*Nein*)

If yes, please specify: \_\_\_\_\_

*wenn ja, welche*

3. Did the vaccine recipient experience allergic symptoms, high fever, or other unusual reactions after an earlier vaccination?

*Traten bei dem Impfling nach einer früheren Impfung allergische Erscheinungen, hohes Fieber oder andere ungewöhnliche Reaktionen auf?*

Yes (*Ja*)

No (*Nein*)

Ask the vaccinator if you wish to know more about protective immunization against meningococcus C (with conjugate vaccine)!

*Falls Sie noch mehr über die Schutzimpfung gegen Meningokokken C – mit Konjugatimpfstoff – wissen wollen, fragen Sie den Impfarzt!*

Please bring your immunization record with you when you come for the vaccination appointment!

*Zum Impftermin bringen Sie bitte das Impfbuch mit!*

**Declaration of consent***Einverständniserklärung***to protective immunization against meningococcus C (with conjugate vaccine)***zur Durchführung der Schutzimpfung gegen Meningokokken C – mit Konjugatimpfstoff*

Name of the vaccine recipient \_\_\_\_\_  
*Name des Impflings*

D.O.B. \_\_\_\_\_  
*geb. am*

I have read and understood the contents of the information leaflet and was informed in detail about the vaccination in the discussion with my doctor.

*Ich habe den Inhalt des Merkblatts zur Kenntnis genommen und bin von meinem Arzt/meiner Ärztin im Gespräch ausführlich über die Impfung aufgeklärt worden.*

I have no further questions.  
*Ich habe keine weiteren Fragen.*

I consent to the proposed vaccination against meningococcus C.  
*Ich willige in die vorgeschlagene Impfung gegen Meningokokken C ein.*

I do not wish to be vaccinated. I was informed of the possible disadvantages of not getting vaccinated.  
*Ich lehne die Impfung ab. Über mögliche Nachteile der Ablehnung dieser Impfung wurde ich informiert.*

Comments \_\_\_\_\_  
*Vermerke*

Place, Date \_\_\_\_\_  
*Ort, Datum*

\_\_\_\_\_  
Vaccine recipient's or guardian's signature  
*Unterschrift des Impflings bzw. des Sorgeberechtigten*

\_\_\_\_\_  
Doctor's signature  
*Unterschrift des Arztes/der Ärztin*